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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,711	02/03/2004	Jeffrey Young	USP2259A-JEF	4135

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,711	YOUNG, JEFFREY	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *7,8 and 26-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on August 23, 2006.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

This application contains Claims 7, 8 and 26-50 drawn to an invention nonelected with traverse on February 10, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-6 and 9-25 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 103

Claims 1-6 and 9-25, as amended, remain rejected under 35 U.S.C. 103(a) as being unpatentable over Li (N). Applicant's argument has been fully considered. However, the rejection stands for the reasons set forth in the previous Office action and for the reasons set forth herein.

In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicant argues that the teachings of Li fail to make obvious the instantly claimed invention because Li merely teaches a tablet having anti-diabetic activity and not a method of administering the reference tablet to a living object with non-insulin dependent diabetes mellitus. Applicant further argues that the teachings of Li do not make obvious the instantly claimed method of treatment because Li does not teach extraction of any of berberine, catalpol or oleanolic acid from any of the claim-designated plants recited in the Markush groups set forth in any of Claims 3-5, as well, as the instantly claimed predetermined amounts of the claim designated ingredients or pharmaceutical forms thereof. However, Applicant's arguments are not found persuasive because the teachings of Li were relied upon because Li taught a sugar-

lowering tablet comprising each of the claim-designated natural herb ingredients of Phellodendron (a berberine ingredient), Rehmannia (a catapol ingredient), figwort or Scrophularia (a catapol ingredient) and honeysuckle or Lonicera (an oleanolic acid ingredient), which can also be used in the making of a food product. Li is silent to the active ingredients contained therein the referenced composition. However, given that Li taught that the referenced tablet has blood sugar lowering effect and is useful for treating diabetes; and given that diabetes is a disease condition that is only known to be a disease condition of living objects; and given that Li taught a composition comprising each of the claim-designated natural herb ingredients of Phellodendron, Rehmannia and Lonicera which are known to be sources of each of the three active ingredients (as evidenced by the claims themselves and as readily admitted by Applicant), the Office deems that the instantly claimed active ingredients of berberine, catapol and oleanolic acid, as well as the claim-designated predetermined amounts of the active ingredients, are inherent to the composition taught by Li, absent evidence to the contrary.

Thus, it would have been obvious to one of ordinary skill in the art and one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to administer the composition taught by Li to a living object in need thereof to provide the instantly claimed method of treating non-insulin diabetes mellitus in a living object in need thereof because at the time the invention was made Li taught, "The invented product possesses obvious effect for reducing blood sugar, and is non-toxic, doesn't result in hypoglycemia, and can be used for curing diabetes, heart diseases, hypertension and hyperlipemia, *etc.*" Given the immediate teaching of Li, it is

clear that Li does not merely teach a tablet having blood sugar lowering effect or merely suggest the administration of the referenced tablet to a living object for the treatment of diabetes mellitus.

With regard to the claim limitations of each of Claims 12-15 and 17 wherein Applicant directs the instantly claimed method to a composition prepared as either a draught in water, a syrup, a cachet and a solution, it also would have been *prima facie* obvious to one of ordinary skill in the art practicing the invention to modify the form of the composition taught by preparing the composition as either a draught in water, a syrup, a cachet or a solution to provide the instantly claimed method because at the time the invention was made each of the claim-designated pharmaceutical forms were known to be conventional and useful vehicles for the delivery of an anti-diabetic agent for the treatment of non-insulin diabetes mellitus, especially since Li taught that the referenced sugar-lowering tablet could be incorporated into other pharmaceutical vehicle forms, such as a food for the delivery of the composition to provide a sugar lowering effect.

Accordingly, the claimed invention as a whole was *prima facie* obvious, given the teachings of Li, especially in the absence of sufficient, clear and convincing evidence to the contrary.

Claims 1-6 and 9-25, as amended, remain rejected under 35 U.S.C. 103(a) as being unpatentable over Li (N) in view of Song et al. (U), Jiang et al. (O), Wang et al. (V), Chen et al. (W), Hsu et al. (X), Takahashi (A*), Grayer-Barkmeijer (U1), Yoshikawa et

al. (V1), Somava et al. (W1), Li et al. (O) and Prasad et al. (X1). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth herein.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, the obvious teachings of Li were relied upon, absent evidence to the contrary, because the

obvious teachings of Li taught a method of treating a living obbject with non-insulin dependent diabetes mellitus comprising a step of administration to a living object a composition comprising a berberine as a first active ingredient and a catalpol as a second active ingredient and an oleanolic acid as a third active ingredient. As set forth above, the obvious teachings of Li did not expressly teach a method of treating non-insulin dependent diabetes mellitus in a subject in need thereof comprising the administration of the instantly claimed ingredients of berberine, catalpol, and oleanolic acid, *per se*. However, even if the claimed method of treatment was not identical to the obvious method of treatment taught by Li, the difference that which is disclosed and that which is claimed are considered to be so slight that the obvious method of treatment is likely to inherently possess the same characteristics of the claimed method in view of the similar characteristics which they have been shown to share. Thus, the method comprising the administration of the claim-designated ingredients from the claim-designated natural herbs would have been obvious to those of ordinary skill in the art within the meaning of USC 103. For instance, while Li expressly teaches a blood sugar-lowering composition comprising Phellodendron, Rehmannia, figwort or Scrophularia and honeysuckle or Lonicera; and, while it is known in the art of chemistry that the plants comprising the Li' composition are good sources for berberine, catapol or oleanolic acid, Li does not expressly teach that the referenced composition comprises each of the claim-designated ingredients extracted from the claim designated plant ingredients. However, it would have been obvious to one of ordinary skill in the art to optimize the composition used in the obvious method of treatment taught by Li by

providing predetermined dosage amounts of the claim-designated ingredients and extract the instantly claimed ingredients from the claim designated plants to provide the instantly claimed method because at the time the invention was made because Song, Jiang and Chen taught methods of treating non-insulin diabetes mellitus comprising the administration of an effective amount of berberine to a living subject in need thereof and Prasad taught Phellodendron as a source of berberine and Chen taught Coptis as a source of berberine; each of Hsu and Takahasi taught a method of treating non-insulin diabetes mellitus comprising the administration of an effective amount of an extract comprising Rehmanniae to a living subject in need thereof and that Rehmanniae comprises catapol; and, Grayer-Barkmeijer taught that the plant genera of Scrophularia (Rehmanniae), Verbascum and Globularia are sources of catapol; and, each of Yoshikawa, Somava and Li taught methods of treating diabetes mellitus in a living subject comprising the administration of effective amounts of a composition comprising an oleanolic acid obtained from beets (Yoshikawa) and Olea (Somava); and Prasad taught that Lonicera (honeysuckle) is a source of oleanolic acid. At the time the invention was made, one of ordinary skill in the art would have been motivated one would have had a reasonable expectation of success to optimize the composition used in the obvious method of treatment taught by Li by providing predetermined dosage amounts of the claim-designated ingredients to provide the instantly claimed method because at the time the invention was made the prior art taught that berberine, catalpol and oleanolic acid are useful in the treatment of non-insulin dependent mellitus and each of the claim-designated ingredient natural herbs have been found useful as

sources of the claim-designated active ingredients and/or useful in the making of compositions exhibiting anti-diabetic effects and intended for the purpose of use in treating living subjects with diabetes mellitus.

Thus, given the obviated method of treating non-insulin dependent diabetes mellitus in a subject comprising the administration of the composition taught by Li and given that the prior art taught that each of berberine, catapol and oleanolic acid are useful ingredients for the making of a therapeutic pharmaceutical composition for the treatment of the claim-designated disease condition and given that the prior art teaches that the claim-designated natural herbs are useful sources of berberine, catapol and oleanolic acid such as the Phellodendron, Rehmanniae and Lonicera comprising the composition taught by Li, the instantly claimed method would have been *prima facie* obvious to one of ordinary skill in the art to optimize the chemical constituents comprising the blood sugar lowering tablet taught by Li and the amounts contained therein to provide an effect result variable to provide a method of treating diabetes mellitus, especially in view of the prior art that teaches that the anti-diabetic functional effect of each of the claim-designated active ingredients are dose dependent. Thus, the instantly claimed invention would have been no more than the addition and/or the replacement of any of the berberine-, catapol- and/or oleanolic acid-containing natural herbs comprising the composition taught by the prior art as being useful in the making of an anti-diabetic composition, each functional equivalent for the other since the prior art taught the beneficial functional effect of natural herbs comprising the claim-

designated ingredients in the making of compositions for use in treating living subjects with diabetes mellitus.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed method because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claimed ingredients taught by the prior art as being obtainable from the claim-designated natural herbs and having anti-diabetic activity to provide the claimed method because the claimed invention is no more than the combining of well known ingredients used in well known methods for treating living subjects with non-insulin dependent diabetes mellitus.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations, as well as the experimental parameters for the manufacturing thereof, are result variables, they would have been routinely

optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references to provide the instantly claimed method of treatment.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele Flood
Primary Examiner
Art Unit 1655

Michele C. Flood

MCF
November 27, 2006